

REMARKS

In the Office Action dated February 13, 2004, the drawings were objected to as failing to comply with 37 C.F.R. §1.84(p)(5) for the reasons noted at page 2 of the Office Action. In response, Figure 4 has been amended to include reference numerals 41-46 that are used at page 7 of the specification, "yes" and "no" had been indicated for the decision blocks 56 and 105 in Figures 5 and 10, respectively, and the text in block 63 of Figure 6 has been corrected.

Claims 1-40 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. The Examiner stated the exact function of the template having data that is populated by information obtained from the patient wearing the implant is not understood. Each of independent claims 1 and 21 has been amended to make clear that the template is used to initialize the filter for subsequent filtering of IEGM signals. This is also an important distinction over the prior art references relied upon by the Examiner, as discussed in more detail below. In the method and cardiac stimulating device of the invention, the template that is used in the filter is derived or created from signals recorded from the patient who will use the cardiac stimulating device. Rather than employing an artificially created template, which may be appropriate for some patients but not others, the template in the filter in accordance with the invention is created using signals from the patient who will use the cardiac stimulating device, thereby enabling the template to embody idiosyncrasies associated with the patient's own cardiac signals that would not be possible if a "one size fits all" template were used, as has been conventional.

The Examiner also questioned whether the maximum deflection that is described in the specification is the peak-to-peak deflection of the QRS waveform, or

only the deflection above or below the base line. In fact, either type of deflection can be used in accordance with the invention, and therefore the specification is enabling with regard to that feature.

The claims are therefore submitted to be in full compliance with all provisions of Section 112, first paragraph.

Claims 5, 6, 9, 10, 25, 26, 29 and 30 were rejected under Section 112, second paragraph, as being indefinite because the Examiner stated the claims as originally written did not include the step of or a device for updating the filter with data from the newly created template. The Examiner stated that the step or structure of "filtering the IEGM signal with the matched filter having the template" is not supported. Applicant believes the above discussion addresses this rejection as well. It should be noted, however, that there is no "updating" of the filter in the sense of repeatedly revising the template. The template is created once, after a suitable number of signals has been recorded for creating the template, and is then used to initialize the filter. The filter with this template is then used for filtering all subsequent IEGM signals. Of course, the entire procedure could be occasionally repeated if it becomes apparent that, due to physiological changes in the patient, the template being employed is drastically ineffective. Such a repetition of the entire procedure, however, does not result in an updating or a revision of the currently-used template, but results in an entirely new template being created, and the filter again being initialized with this new template.

Claims 5, 6, 9, 10, 25, 26, 29 and 30, therefore, are submitted to be in full compliance with all provisions of Section 112, second paragraph.

Claims 1, 19 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Farrugia et al. Claims 11, 12, 14-18, 21, 31, 32, 34 and 36-40 were rejected under 35 U.S.C. §103(a) as being unpatentable over Farrugia et al in view of Sweeney et al. Claims 13, 33 and 35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Farrugia et al in view of Sweeney et al, further in view of Errico et al.

These rejections are respectfully traversed for the following reasons.

Much of the above discussion is relevant for distinguishing the subject matter of claims 1-40 over the teachings of the Farrugia et al reference. The method and apparatus disclosed in that reference employ a neural network for discriminating between tachycardia of a physiological origin, and tachycardia of a pathological origin. Since these types of tachycardia may have similar rates, the morphology of the IEGM signal is used as a basis for the discrimination. The neural network is trained as to the morphological characteristics of the patient's IEGM over time, and therefore becomes able to make the aforementioned discrimination. Therefore, the ultimate goal in the method and apparatus disclosed in the Farrugia et al reference is to classify an incoming waveform as being of a particular type (dependent on its morphology).

As noted above, the method and apparatus disclosed and claimed in the present application are for a completely different purpose, namely to create a template that is then used in a filter to filter all subsequent IEGM signals that are recorded after the template is created and used to initialize the filter. Since the filter in the method and apparatus of the invention is a morphology-sensitive filter, it is unavoidable that, at least in the dependent claims, certain morphological

characteristics, similar to those discussed in the Farrugia et al reference, will be employed or analyzed. There are a limited number of morphological factors or features associated with a cardiac signal, and therefore it is not surprising that the subject matter disclosed and claimed in the present application and the subject matter disclosed in the Farrugia et al reference make use of similar features. As noted above, however, there is no teaching whatsoever in the Farrugia et al reference to create a template for a filter in any manner, regardless of whether similar morphological characteristics of cardiac waveforms are discussed in that reference. The teachings of the Farrugia et al reference are directed to classification of incoming waveforms, rather than filtering incoming waveforms.

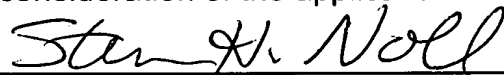
Moreover, as noted above the template is created once, and is then used to initialize the filter for filtering all subsequent IEGM signals. There is no "training" or continuous refinement of the template, as is essential in the Farrugia et al reference in the context of the neural network that is employed therein.

Since the Farrugia et al reference does not disclose or suggest the creation of a template for a filter, nor initialization of a filter with that template for filtering subsequent IEGM signals, the subject matter of claims 1, 19 and 20 would not have been obvious to a person of ordinary skill in the field of cardiac stimulating device design based on the teachings of the Farrugia et al reference.

As to the secondary references, (Sweeney et al and Errico et al) that were relied upon to reject the remaining claims, Applicant does not have a serious disagreement with the Examiner's statements regarding the teachings of those references. Neither of those references, however, discloses or suggest the creation of a template for initializing a filter that will be used to filter all subsequently-recorded

IEGM signals. Therefore, even if the Farrugia et al reference were modified in accordance with the teachings of one or both of Sweeney et al and Errico et al, the subject matter of the claims against which those references were applied would not have been obvious to a person of ordinary skill in the field of cardiac stimulating device design based on the teachings of those references.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.



(Reg. 28,982)

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